DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

Mr. Scott Beckley
Vice President
TPC Advanced Technology, Incorporated
18525 East Gale Avenue
City of Industry, California 91748

Re: K071485
Trade/Device Name: AdvanceCAM Intra Oral Camera System and Accessories
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: April 17, 2007
Received: May 30, 2007

Dear Mr. Beckley:

This letter corrects our substantially equivalent letter of August 28, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

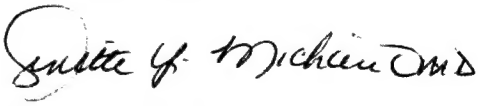
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AdvanceCAM Intra Oral Camera System and accessories found to be substantially equivalent:

MODEL	DESCRIPTION
AIC 888	Optic unit
AIC 810	Docking station
AIC 700	Analog to digital converter
AIC 705	Wireless analog to digital converter
AIC 720	Analog to digital converter
AIC 750	Analog to digital converter
AIC 650	Docking station
AIC 665	Wireless docking station
AIC 600	Docking station
AIC 900	Wireless transmitter
AIC 805	Docking station
AIC 815	Wireless docking station
AIC 899	Optic unit
AIC 835	Wireless docking station
AIC 825	Docking station

18525 E. Gale Ave.
City of Industry, CA 91748
800.560.8222
626.810.4337
Fax: 626.810.4245

Dental Equipment Manufacturer
Chairs, Units, Lights, Intraoral Cameras, etc.

Indications for Use

510(k) Number (if known):

Device Name: AdvanceCAM Intra Oral Camera System and accessories

Indications for Use:

AdvanceCAM intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in decribing the dental procedure being performed as well as showing the results

Prescription Use ✓ and/or Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071485